



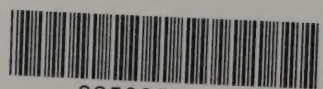
HOUSE OF LORDS

European Union Committee

22nd Report of Session 2008–09

**The revision of the
EU Directive on the
protection of
animals used for
scientific purposes**

Volume I: Report



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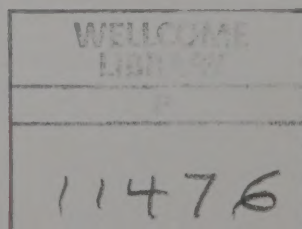
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The telephone number for general enquiries is 020 7219 5791. The Committee's email address is euclords@parliament.uk



CONTENTS

	<i>Paragraph</i>	<i>Page</i>
Summary		5
Chapter 1: Introduction	1	7
The Inquiry	1	7
Existing Controls in the UK, under the Animals (Scientific Procedures) Act 1986	6	8
European Commission's proposed revision of Directive 86/609/EEC	9	8
Rationale for a revised directive	12	9
Box 1: Statistical Information about the Use of Animals in Scientific Procedures		10
Chapter 2: General provisions	16	11
Scope	16	11
Severity classifications	24	12
Box 2: Extract from July 2009 report of expert working group on severity classifications		13
Re-use	27	13
Care and accommodation standards	32	14
Promotion of the 3Rs	41	16
Box 3: National Centre for the 3Rs		16
Chapter 3: Use of non-human primates in research	48	18
Limitation of use to research into life-threatening or debilitating conditions	48	18
Box 4: Statistical Information about the Use of Non-Human Primates in Britain		20
Figure 1: Regulated use of non-human primates (NHPs) for research and testing in Britain, 1999–2008		20
Limitation of use to offspring of animals bred in captivity	57	21
Box 5: Supply of F2 macaques: background information		22
Chapter 4: Data-sharing and authorisation	64	23
Data-sharing	64	23
Authorisation	73	24
UK regulatory environment	78	25
Authorisation or notification	84	26
Authorisation and competitiveness	89	27
Implementation—inspection and review	93	28
Chapter 5: Conclusions and Recommendations	100	30
Scope	101	30
Severity classifications	105	30
Re-use	107	30
Care and accommodation standards	108	30
Promotion of the 3Rs	109	31
Use of non-human primates in research	110	31
Data-sharing	112	31
Authorisation	114	31
Inspection and review	117	32

Appendix 1: Sub-Committee D (Environment and Agriculture)	33
Appendix 2: List of Witnesses	35
Appendix 3: Call for Evidence	36
Appendix 4: Trends in use of animals in scientific procedures in Britain	38

NOTE: References in the text of the report are as follows:

(Q) refers to a question in the oral evidence

(p) refers to a page of written evidence

(para) refers to a paragraph in the report

The Evidence of the Committee is published in Volume II (HL Paper 164-II)

SUMMARY

Using animals in scientific procedures allows researchers to gain a better understanding of the nature of diseases, and of possible treatments, in order to improve tackling these diseases in human sufferers. There is significant public concern about such use of animals, in the UK and elsewhere, even though these procedures are subject to control regimes which have been in place for some years.

In 1986, the European Community adopted Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. In the same year, the UK Parliament agreed the Animals (Scientific Procedures) Act 1986, updating older legislation controlling the use of animals for scientific research and serving to implement the Directive.

In November 2008, the European Commission published a proposed revision of the 1986 Directive. The Commission considered that the time had come to tackle inconsistent implementation of the earlier Directive, in order to strengthen animal protection and to bring about a level playing-field across the EU for companies and institutions carrying out research.

There is a widespread recognition that the UK has achieved and maintained high standards of animal welfare in its controls over scientific procedures. In the process of tackling the inconsistencies that have developed since adoption of the 1986 Directive, the proposal contains some aspects which go beyond the controls currently in place in the UK.

This is true, in particular, in relation to the proposed extension of scope, limitations on the re-use of animals, requirements for the care and accommodation of animals, possible restrictions on the use of non-human primates, and more burdensome administration.

We share in the general consensus that a revised Directive should now be agreed and implemented effectively. Developments both in scientific techniques and in public opinion in the last 20 years must inform the work of revision. We are clear that the result must be a levelling-up of standards of animal welfare across all Member States, with no weakening of standards in the UK. We see it as of paramount importance to ensure that a new Directive is implemented consistently in all Member States and that the Commission is active in bringing this about.

Where the Commission's proposal implies a tightening of controls beyond the present position in the UK, careful consideration of the feasibility and impact of these changes is essential and may point to some adjustment.

We see a need to extend the timescale both for implementing new care and accommodation standards in the academic sector, and for introducing the proposed stocking densities for rodents at breeding establishments. Similarly, we consider it crucial that the feasibility of the time-limits proposed for phasing out the use of non-human primates which are not the second generation bred in captivity should be reviewed, on a species-by-species basis.

Conversely, as regards the proposed limitation of the use of non-human primates to research related to life-threatening or debilitating conditions, we are persuaded that this strikes the right balance between animal welfare and scientific research. While the wording of this limitation may be clarified to permit research into conditions which have a substantial impact on patients' day-to-day functioning, we look to the new Directive to place tighter limits on the use of non-human primates than on the use of other species.

We support the proposed authorisation requirements, recognising that authorisation processes contained in the proposal should be justified by the scientifically demonstrated needs of animal welfare.

Finally, in the interests of ensuring common standards, we firmly endorse arrangements for effective national inspection in Member States, and for a robust role for the Commission in monitoring those arrangements. Without this, we fear that a new Directive will do little to remedy the widely varying approaches of Member States, including standards of animal welfare, which currently exist.

The revision of the EU Directive on the protection of animals used for scientific purposes

CHAPTER 1: INTRODUCTION

The Inquiry

1. Current UK and EU legislation on the protection of animals used in scientific procedures has been in place for more than 20 years.
2. In 1986, the European Community adopted Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. In November 2008, the European Commission published a proposal¹ to revise Directive 86/609/EEC. In May 2009, the European Parliament gave a First Reading to the document and proposed a number of amendments.² Sweden made it a priority of its EU Presidency to advance negotiations on this proposal during the second half of 2009.
3. This inquiry was conducted by Sub-Committee D, whose members are listed in Appendix 1, with their declared interests. We received evidence from the witnesses listed in Appendix 2, to all of whom we are grateful. The call for evidence, issued in April 2009, is reproduced in Appendix 3. As well as questioning witnesses in meetings at Westminster, we visited a research facility run by King's College London, and we talked to stakeholders in Brussels. The Sub-Committee was assisted by their Specialist Adviser, Dr Jane Smith.
4. On 17 July, the Chairman of the Select Committee on the European Union wrote to Lord West of Spithead, Parliamentary Under Secretary of State at the Home Office, to set out our emerging conclusions on the proposed revision of Directive 86/609/EEC.³ While we had not then concluded our inquiry, we wanted to put these views in the public domain before the Swedish Presidency moved negotiations ahead significantly.
5. This report is consistent with our earlier letter, but we have subsequently received further correspondence, and heard evidence, from Lord Brett, Parliamentary Under Secretary of State at the Home Office; and we have also taken account of recent developments in discussions under the Swedish Presidency. **We make this report to the House for debate.**

¹ COM(2008)543.

² 2008/0211(COD).

³ The letter is reprinted at p 197 of Volume II.

Existing Controls in the UK, under the Animals (Scientific Procedures) Act 1986

6. In the same year as the adoption of Directive 86/609/EEC, the Animals (Scientific Procedures) Act 1986 was enacted in the UK, which put in place the current system of controls on scientific work on living animals and served to implement the Directive.⁴
7. The Act regulates any experimental or other scientific procedure applied to a “protected animal” which may have the effect of causing that animal pain, suffering, distress or lasting harm. “Protected animals” are defined as all living vertebrate animals, except man, plus one invertebrate species, *Octopus vulgaris*: the definition extends to foetal, larval or embryonic forms that have reached specified stages in their development.
8. Three types of authorisation are required for all work controlled by the Act. The procedures must be part of a programme of work authorised by a project licence; the person applying the regulated procedures must hold a personal licence; and the place where the work is to be done must hold a certificate of designation. No work may be done unless the procedure, its purpose, the animals used and the place are specifically authorised. Box 1 provides statistical information about the use of animals in scientific procedures. Additional information is contained in Appendix 4.

European Commission’s proposed revision of Directive 86/609/EEC

9. In publishing the proposed revision of the 1986 Directive, the European Commission identified the following main objectives for the proposal:
 - to rectify wide variations in the implementation of the 1986 Directive and ensure a level playing-field within the EU for industry and the research community by laying down harmonised common rules;
 - to strengthen the protection of animals used in scientific procedures; and
 - to promote the “3Rs”, that is, the replacement, reduction and refinement of the scientific use of animals, through the development and implementation of relevant methods.
10. The main new provisions in the proposal included:
 - a regulatory framework in which individuals, places and projects using animals in scientific procedures must be authorised in advance;
 - a requirement that Member States establish an inspection system to monitor and enforce compliance by establishments with the requirements of the Directive;
 - a requirement that each establishment have a permanent ethical review body to advise on the ethical treatment and welfare of animals and the 3Rs; and to carry out annual reviews of certain projects;
 - classification of procedures according to their severity (in terms of the pain, suffering, distress and lasting harm to the animals);

⁴ Operation of the Act is not a devolved responsibility in Great Britain. The Home Office administers the legislation in England, Scotland and Wales; the Act is separately administered in Northern Ireland.

- a ban on the use of great apes (gorillas, chimpanzees, bonobos and orangutans);
 - other restrictions on the use, breeding and acquisition of non-human primates;
 - promotion of the 3Rs; and
 - a requirement that Member States apply prescribed minimum standards of animal care and accommodation.
11. Other provisions dealt with the extension of the Directive's coverage, in terms of species and their developmental stages, and purposes for which animals are used; the sharing of data relating to scientific procedures; and the establishment of national reference laboratories to assist in the validation of alternative methods.

Rationale for a revised directive

12. The objectives which the Commission has cited for the proposal include, alongside the promotion of animal welfare, the application of harmonised common rules across the EU. The Commission's representative, and other witnesses, agreed that implementation of the 1986 Directive had been inconsistent across Member States. For the Commission, Ms Susanna Louhimies commented that the biggest differences between States related to the authorisation process, and standards for care and accommodation (Q 8).
13. We found a wide-ranging consensus that, against this background, and given the importance of animal welfare concerns, the time was right to revise the 1986 Directive. Key elements of the Commission's proposal are that in all Member States animal procedures should be subject to a requirement for prior authorisation, and that this should include an ethical review process.
14. Such a regime is close to the arrangements that have applied in the UK under the 1986 Act. Experience of the UK approach no doubt underlay the support voiced to us for these elements of the proposal. For example, speaking for the Association of the British Pharmaceutical Industry (ABPI) Professor Tim Hammond described the introduction of ethical review as a "very positive thing" (Q 58); while Dr Maggy Jennings said that the Royal Society for the Prevention of Cruelty to Animals (RSPCA) was "very supportive" of local ethical review processes (Q 182).
15. We are clear that, since 1986, the UK has put in place arrangements which have promoted good standards of animal care and use; but more generally there have been inconsistencies in the implementation of the 1986 Directive which have been left unchecked for too long. At the same time, new legislation should take account of developments in science and the understanding of animal welfare over the last 20 years which, in our view, provide a clear impetus towards higher standards **We agree that the 1986 Directive should be revised: a new Directive should contain effective safeguards to ensure consistent implementation.** We return to these issues in Chapter 4.

BOX 1

Statistical Information about the Use of Animals in Scientific Procedures

In November 2007, the European Commission published its 5th statistical report on the number of animals used for scientific purposes in the EU Member States.^(a) The report showed that, in 2005, a total of 12.1 million animals were used in the 25 EU Member States. Of this total, rodents and rabbits made up 77.5%; fish, amphibians and reptiles 15%; birds 5.4%; horses, donkeys and crossbreeds, pigs, goats, sheep and cattle 1.1%; carnivores 0.3%; and non-human primates 0.1%.^(b)

Within the total of 12.1 million animals used, the largest proportions were reported from France (2.3 million), Germany (1.8 million) and the UK (1.9 million).

In the UK, the Home Office produces an annual publication of statistics of scientific procedures on living animals in Great Britain. The basis on which the Home Office statistics are compiled differs from that used in the Commission’s statistical reports: thus, for 2005 the Home Office statistics showed that slightly under 2.9 million scientific procedures were started in that year. This number is higher than that recorded in the EU statistics, largely because the UK (but not the EU) regulates and reports the use of animals bred for the maintenance of colonies of genetically modified or harmful mutant animals. The number of scientific procedures performed is higher than the number of animals used for the first time, because animals are sometimes re-used.

In July 2009, the Home Office published statistics of scientific procedures on living animals in Great Britain in 2008^(c): just under 3.7 million scientific procedures were started in 2008. Of this total, all rodents together accounted for 77%; fish and birds were used in, respectively, 17% and 3% of procedures; and dogs, cats, horses and non-human primates were collectively used in less than 1% of all procedures.

The number of animals used in scientific procedures in the UK has declined from a high of over 5.5 million in the 1970s to under 3 million in the 1990s, levelling off at around 2.6 million in 1997–2001. Since 2001 there has been an upward trend in the use of animals as recorded in the statistics. A rise in the breeding of animals for the maintenance of colonies of genetically modified or harmful mutant animals accounts for a significant part of this increase. In 2008, such breeding accounted for 38% of the total recorded use of animals. This and the other “primary purposes” for which animals were used in scientific procedures in 2008 are shown in the table below:

Primary purpose of using animals in scientific research	% total procedures in 2008
Breeding to maintain colonies of genetically modified or mutant animals	38
Fundamental biological research	32
Applied studies for human or veterinary medicine/dentistry	26
Protection of man, animals or environment	2
Direct diagnosis of disease	1

(a) COM(2007)675.

See:<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007DC0675:EN:NOT>

(b) Non-human primates include old world monkeys, such as macaques, and new world monkeys, such as marmosets; no great apes were used.

(c) See: <http://www.homeoffice.gov.uk/rds/pdfs09/spanimals08.pdf>

CHAPTER 2: GENERAL PROVISIONS

Scope

16. The proposal extends the scope of the Directive in a number of ways. Coverage is widened to include certain classes of live invertebrate animals (specified in Annex I): cyclostomes (hagfish and lampreys),⁵ cephalopods (such as octopus and squid) and crustacean decapods (for example, crabs, lobsters and shrimp). In addition, coverage is extended to animals bred specifically so that their tissues and organs may be used for scientific purposes. In the case of live non-human vertebrate animals, the scope of the Directive is extended to include independently feeding larval forms and embryonic or foetal forms from the last third of their normal development.
17. Evidence which we heard raised questions about the appropriateness of the proposed extension to invertebrates. The nub of the issue is the strength of available evidence to show that such creatures feel pain and can suffer: "sentience". Sir Leszek Borysiewicz, Chief Executive of the Medical Research Council (MRC), said that the evidence base was very limited in some cases. He voiced concern about the implications for research of extending coverage: "... many of these animals will also form the basis on which we can eventually look for substitutions of non-human primates and other species, so that if you begin to restrict their potential use and investigation in this area it does cause major problems for reasonable movement in the 3Rs direction" (Q 245). He considered that, while there was some limited evidence of sentience in the case of cephalopods, there was very little for decapods.
18. For the RSPCA, Mr Bowles agreed that the evidence of sentience for cephalopods and decapods was inconclusive. However, he pointed out that other countries (Austria, New Zealand and Norway) had recently extended protection to these species under their domestic legislation. Since the RSPCA's view was that, in areas of uncertainty, the benefit of the doubt should be given to the animals, they supported the Commission's proposals (Q 166).
19. We consider that the scope should be linked as closely as possible to broadly accepted evidence of sentience; in the current state of inconclusive knowledge about invertebrates, decisions about whether or not to include individual species cannot be firmly founded. **Based upon the available scientific knowledge about sentience, we consider that, while cephalopods should be included, decapods should be excluded. We also take the view that independently feeding larval forms of invertebrates should be excluded. We consider that cyclostomes should be included.**
20. Article 48 of the proposal deals with the adaptation of certain Annexes (II to VII) to technical progress.⁶ However, that Article contains no provision to amend the list of invertebrates in Annex I. When we took evidence from Lord Brett, we were told that the UK had raised the possibility that Article 48 should be amended to include Annex I, and that the Commission,

⁵ We note from Home Office advice, however, that cyclostomes should properly be classified as vertebrates.

⁶ Any such adaptation is subject to the regulatory procedure with scrutiny referred to in Article 51(4).

supported by the Council's Legal Service, had advised that, since Annex I formed part of the provisions on the scope of the proposal, it was not amendable through the procedure applicable under Article 48: any such amendment should be made through the co-decision procedure. **We think that it should be possible for the emergence of new scientific evidence pertaining to sentience to lead relatively readily to the inclusion (or exclusion) of invertebrate species in the control regime of the Directive; we would hope that further consideration of the framing of these provisions would allow a more flexible approach to be followed.**

21. Independently feeding larval forms and embryonic or foetal forms (from the last third of their normal development) of live non-human vertebrate animals would also be included. For the latter forms, this proposal differs from the approach taken in the UK, where, under the 1986 Act, protection is provided from half-way through the gestation or incubation period for the relevant species. We see no reason why the UK would need to amend its approach if the Commission's proposal were adopted, although we understand that the impact elsewhere in the EU may well be greater. We were told by EFPIA of their concern about the implications for the use of fertilised chicken eggs in vaccine production (Q 441). **We have seen no evidence to suggest that the UK's approach is unjustified; in the interests of consistency, we support the proposal.**
22. The bioscience sector commented on the proposed extension to cover animals bred for organs and tissues: "Extension of the scope to all such animals would cause a major increase in regulatory burden with no animal welfare benefit. Indeed it may adversely affect welfare in that raising the level of bureaucracy and cost around using isolated organs and tissue removes an incentive to use them instead of using living animals" (p 25). The Home Office pointed out that the welfare of these animals is (for the most part) already covered by provisions on animal care and accommodation and general animal welfare legislation (p 194).
23. **We consider that the provisions of the Directive should be amended to ensure that the breeding and humane killing of animals for their tissues and organs should not be regarded as a "project" within the terms of the Directive. While the care and welfare of these animals should be ensured, we regard it as disproportionate to require that work involving them should be subject to the authorisation processes required of projects.**

Severity classifications

24. As published in November 2008, Article 15 of the proposal provided that all procedures should be designated in accordance with a system of severity classifications: "up to mild", "moderate", "severe" or "non-recovery". A number of other provisions in the proposal depended upon this classification system. However, the proposal left the definition of the criteria for the classifications to be determined at a later date. All our witnesses who commented on this issue stressed the need for those definitions to be spelt out as part of the revised directive in order to provide some clarity about the impact of those provisions of the Directive that are reliant on the definitions; **we agree.**
25. Over the summer, work on this has been taken forward by the Commission. In July, an expert working group published a report which offered definitions

for the four categories mentioned above.⁷ (See Box 2) **We consider that the definitions proposed by the working group could appropriately be adopted in the revised directive.**

26. Article 15 of the proposal also provided that procedures classified as “severe” should not be performed if the pain, suffering or distress of the animal was likely to be prolonged; and in the UK “any procedure likely to cause severe pain or distress that cannot be alleviated” will not be licensed. We note that two of the amendments⁸ by the European Parliament would weaken the provision in Article 15, by allowing for such procedures to go ahead in exceptional circumstances. **We regard these amendments as implying a lower level of animal welfare than is currently maintained, and we would see any such change as unacceptable.**

BOX 2

Extract from July 2009 report of expert working group on severity classifications

Definitions

The proposal has 4 severity categories; non-recovery, mild, moderate and severe. These should be defined as follows:

Non-recovery:

Procedures, which are performed entirely under general anaesthesia from which the animal shall not recover consciousness.

Mild:

Procedures on animals as a result of which the animals are likely to experience short term mild pain, suffering or distress. Procedures with no significant impairment of the wellbeing or general condition of the animals.

Moderate:

Procedures on animals as a result of which the animals are likely to experience short term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress. Procedures that are likely to cause moderate impairment of the wellbeing or general condition of the animals.

Severe:

Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress. Procedures, that are likely to cause severe impairment of the wellbeing or general condition of the animals.

Re-use

27. Re-use occurs when, after completion of one protocol, “an animal is used again in the same or a different protocol, when a previously unused animal could have been used to meet the experimental objectives satisfactorily”.⁹

⁷ Final report of the expert working group on severity classification of scientific procedures performed on animals. See: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/report_ewg.pdf

⁸ Joint amendments 70 and 175 to Article 15(2) of the text.

⁹ Home Office (2008): Animals (Scientific Procedures) Act 1986. Use, continued use and re-use of animals.

28. Article 16(1) of the proposal permits re-use of animals that have been subjected to “up to mild” procedures, provided that subsequent procedures are also “up to mild” or “non-recovery”. Article 16(2) provides a derogation, in that, where the first procedure is “moderate” or “severe”, animals may be re-used once in “up to mild” procedures.
29. These restrictions are intended to limit animal suffering, but for some specific types of work Article 16(2) could run counter to this aim. For example, Article 16 would prevent the testing of several different new medicines using “up to mild” dosing procedures in dogs that have been surgically implanted with telemetry devices (a “moderate” procedure) to measure parameters such as blood pressure and body temperature remotely. The restriction would mean that, after one re-use, no further tests could be carried out using such a dog, and another animal would have to undergo surgery to implant a telemetry device: there would thus be an increase both in the number of animals used and in the level of suffering. Sir Mark Walport, Chief Executive of the Wellcome Trust, offered this example in referring to what he saw as fairly general agreement that the limitations on re-use might be counterproductive to animal welfare (Q 242).
30. For the RSPCA, Dr Maggy Jennings acknowledged that, in excluding re-use of animals that had undergone moderate procedures, the proposal “could result in a considerable increase in animal use in certain areas, and that would concern us.” The RSPCA would be prepared to consider the possibility of re-use of animals used in moderate procedures, where that was in the interests of animal welfare, and depending on an appropriate definition of “moderate” and on the existence of a well-monitored system of control (Q 177).
31. **The re-use provisions must be amended in order to avoid unintended consequences for animal welfare. As presented in the Commission’s proposal, the provisions would be likely, in certain specific circumstances, to increase the number of animals and degree of suffering that would need to be used.**

Care and accommodation standards

32. Annex IV of the Commission’s proposal specifies a range of care and accommodation standards which are intended to reflect the specific needs and characteristics of the species included. As Ms Louhimies explained to us, differences between Member States in their animal care and accommodation requirements have been one of the most significant examples of the inconsistent implementation of the existing Directive.
33. The care and accommodation standards set out in the proposal would therefore be mandatory on those who keep animals for scientific procedures. In their essence, the standards are those which were previously elaborated as Council of Europe guidelines,¹⁰ although in that form numerical specifications were accompanied by explanatory text. In 2007 those guidelines had already been incorporated in the existing Directive, as Annex II, albeit on an advisory basis.

¹⁰ Appendix A of the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (ETS No. 123): Guidelines for accommodation and care of animals (Article 5 of the Convention), as amended 15 June 2006

34. The Universities Federation for Animal Welfare pointed out that much of the advice provided in that Annex was aimed at preventing husbandry errors, and that in the current proposal Article 32 and Annex IV have converted an advisory document into a mandatory one, while losing much of the text: “Because species-specific qualifying text and general advice has been omitted, the proposed Annex IV has lost vital information that qualifies the tables, could be misleading and is likely to result in incidences of poor animal welfare” (p 250).
35. We heard conflicting views about the scientific justification for the standards. On the one hand, representatives of the academic community said that the scientific basis “was virtually absent” (Q 250). On the other, the RSPCA told us that the standards had been reached “over an eight-year period and involved experts in animal welfare of each of the species in question from all of the main stakeholder groups” (Q 188). However, the RSPCA made their view clear that the text which accompanied the Council of Europe guidelines should be included in the proposed revision.
36. Speaking for the National Centre for the 3Rs (NC3Rs), Dr Mark Prescott took a similar line: “we are quite comfortable with the proposals as they stand and would support them as mandatory minima for the care and accommodation of animals across Europe” (Q 292). However, Dr Prescott also acknowledged that some sectors might need longer than others to move to the new standards.
37. Ms Louhimies acknowledged that academic research establishments might need longer to adapt. She pointed out that the impact assessment accompanying the Commission’s proposal stated that academic research would require longer transitional periods for certain elements than the private sector (Q 36).
38. The ABPI’s representatives voiced particular concern about standards for housing rodents and rabbits: “... if they were adopted as currently indicated in the draft we would be losing a very considerable amount of capacity for rodent and rabbit stock, and that is even in comparison to the current well-enforced standards in the UK code of practice” (Q 129). The Laboratory Animal Breeders Association (LABA) of Great Britain reinforced this concern. LABA said that space allocation standards proposed for stock rodents significantly exceeded those required under current UK codes of practice, and that “the operational changes required will demand re-equipping and construction of new facilities to breed and supply the same number of animals” (p 234). In its impact assessment, the Home Office comments that the standards would require additional investment at some facilities, and that without such investment there would be a reduction in production and holding capacity, and hence research capacity.
39. The evidence that we received indicated that the care and accommodation standards have been anticipated for some time. However, for the Home Office, Dr Jon Richmond said that their conversion from aspirational to mandatory standards would pose challenges to some of those affected (Q 486). We think it right to strike a note of caution about the timescale proposed for their achievement by academic research establishments; **we consider that the timescale for implementation in the academic sector should be extended.**
40. We also draw attention to concerns that have been expressed over the practicalities of the stocking densities proposed for rodents at breeding

establishments, which could well have significant cost implications because of the need to replace or rebuild cages and, as a result, to invest in new infrastructure to accommodate additional cages. **Since it is unclear that the resulting increase in cage sizes will offer any measurable benefit to the welfare of these animals, we think that the timescale for the introduction of these stocking densities should be extended. More generally, we accept the case made to us that explanatory text which accompanied the standards as first embodied in Council of Europe guidelines should be restored.**

Promotion of the 3Rs

41. The Commission has specified as one of the key objectives of the proposal the promotion of the 3Rs: the replacement, reduction and refinement of the scientific use of animals, through the development and implementation of relevant methods. No evidence that we received disagreed with the importance of this objective. We were particularly interested to hear from representatives of the UK's own NC3Rs (see Box 3), who explained that the Centre had been launched in 2004 in line with a recommendation from an earlier House of Lords inquiry.¹¹ Dr Vicky Robinson, the Chief Executive, welcomed the explicit reference to the 3Rs in the proposal, while voicing reservations about some of its detailed aspects (Q 274).

BOX 3

National Centre for the 3Rs

In the UK, the National Centre for the 3Rs (NC3Rs) is largely funded by the Government through the Medical Research Council, the Biotechnology and Biological Sciences Research Council, and the Home Office and also receives funding from the pharmaceuticals and chemicals industry and the Wellcome Trust.

There are two main elements to the NC3Rs' work:

- as a research funding body, investing in research in universities and in industry. The NC3Rs has awarded 41 grants to date totalling £8 million across a whole range of disciplines in the life sciences. The aim is delivering advances in the 3Rs; and
- as an instigator of activities led by the office, focused on working with scientists and universities and industry, as well as with regulators, learned societies and research funding bodies, to look at new opportunities for the 3Rs and to provide a safe forum for data-sharing and for the exchange of ideas, knowledge and concerns.

42. The proposal provides specifically that each Member State should set up a national reference laboratory for the 3Rs. Article 46 foresees that each such laboratory would carry out a range of tasks, including validating alternative methods; communicating information on the availability and application of such methods; providing scientific and technical assistance for the acceptance and implementation of such methods; and providing training in their use.
43. We encountered a good deal of scepticism about the proposal for each Member State to set up a national reference laboratory. Dr Robinson

¹¹ House of Lords Select Committee on Animal Procedures: Report (HL Paper 150, Session 2001–02).

suggested that the universal adoption of one model could mean that inputs from across the whole field of research would be missed: “There is not going to be a one fit approach. We are going to need to exploit tissue engineering, systems biology and so on. My concern would be that you could not have that breadth of experience in one laboratory. I think that it would end up being a white elephant” (Q 277).

44. The same point was made to us by Sir Leszek Borysiewicz (MRC) who said that it had been an achievement of the UK’s 3Rs programme that it had engaged scientists who fully understood the area in which they were working: “... it is the scientists who work in a particular condition or in a particular field or a particular physiological system who are often best placed to advise and consider what are the best experiments to be done to consider replacement, rather than an arbitrary creation of a national physical centre which brings in experts who may not be expert in the specific field that you are trying to replace” (Q 254). Supplementary evidence from the UK bioscience sector reinforced this point, by stating that: virtually all the “alternative” methods cited by antivivisection groups had been developed and funded from within the mainstream scientific community, including the development of functional magnetic resonance imaging, microdosing, and in-vitro and in-silico techniques.
45. Some witnesses suggested that the role of the existing European Centre for the Validation of Alternative Methods (ECVAM) could be expanded. For the RSPCA, for example, Mr Bowles said that, while ECVAM had been established since 1992, its focus had been on replacement, in particular the validation of alternative methods in the field of toxicity testing. The RSPCA supported an expansion of the role of ECVAM, to co-ordinate the greater efforts which Member States would make to promote the 3Rs (Q 199). We sensed less enthusiasm from the representatives of EFPIA, who recognised that ECVAM had hitherto had only a limited capability, and who spoke of the UK’s NC3Rs as “a perfect example of dissemination of information to the end users and the regulatory authorities and of good collaboration between different players” (Q 450).
46. We also heard arguments that the proposal did not go far enough. In particular, for the Dr Hadwen Trust,¹² Ms McIvor argued that the revision of the directive provided the opportunity for an ambitious strategy for the 3Rs to be developed and implemented across the EU; and that such a strategy would best be delivered through “maximum use ... of the national centres and the national laboratories ... co-ordinated at EU level” (Q 318).
47. **We support the general promotion of the 3Rs**; it is implicit in our approach that the continued use of animals in scientific procedures is acceptable only where no alternative methods can be identified. **The specific proposal that national reference laboratories be set up is too prescriptive**; we see a risk that such a centralised model would fail to draw on the expertise and innovation that are found in the wider scientific community. **We are persuaded that a system of national centres along the lines of the UK’s National Centre for the 3Rs might well be a better route to follow.** ECVAM plays a valuable role and it may be able to assist in the important task of sharing best practice and information on the 3Rs between EU countries.

¹² The Dr Hadwen Trust is a medical research charity that funds and promotes exclusively non-animal techniques to replace animal experiments.

CHAPTER 3: USE OF NON-HUMAN PRIMATES IN RESEARCH

Limitation of use to research into life-threatening or debilitating conditions

48. Within the whole field of the use of animals for scientific procedures, there is particular sensitivity over the use of non-human primates (though this accounts for less than 1% of all procedures). This is an issue of particular concern to the general public. Moreover, the biological similarity of non-human primates to human beings, and their highly developed social skills, heighten animal welfare issues while simultaneously strengthening research interest in these animals, as models for humans in scientific research and testing.
49. The major use of non-human primates is in evaluating the safety or efficacy of pharmaceuticals; in Britain in 2008, for example, 82% of the use of macaques was for this purpose. (See Box 4 and Figure 1) The Commission's proposal takes as its starting-point that, given the current state of scientific knowledge, there is an unavoidable need to use non-human primates in biomedical research. However, the proposal also includes special restrictions. The use of great apes is prohibited (as is already the case in the UK). There are restrictions on the supply of other non-human primates, which we consider below. And, in particular, Article 8 limits the use of other non-human primates (such as marmosets and macaques) to research related to "life-threatening or debilitating clinical conditions in human beings". This approach of defining the circumstances of use differs from the UK position, where non-human primate use is authorised only when the Home Office, as the regulatory authority, is satisfied that there is sufficient justification, no alternative, and when purpose-bred animals are used.
50. We received a range of views on the likely effects of the restriction in Article 8, and about the difficulty of drawing a clear and workable line around areas of research where non-human primates may be involved. In their written evidence, the RSPCA said that it would have no impact because "the scientific community argues that all the research currently done on primates is for serious medical conditions", so that such research would still be permissible (paragraph 14 of evidence). Conversely, speaking for the ABPI, Professor Hammond said that the definition of the restriction was problematic: "To assume that any project that is done is justified purely on the basis that it will affect a specific disease fails to understand the way in which research operates" (Q 101).
51. Ms Magda Chlebus, Director of Animal Welfare for the European Federation of Pharmaceutical Industries and Associations (EFPIA), questioned the need for specific restrictions in this, and other, areas: "If we consider all existing safeguards provided by ethical review, scientific justification, harm benefit assessment, retrospective reviews, all of these layers of controls make any additional limitations, like the ones on non-human primates, completely redundant" (Q 394). A similar view was expressed to us by the Chief Executive of the NC3Rs, Dr Vicky Robinson, who considered that the wording "debilitating and life-threatening" was unhelpful, not least because specific formulations could be interpreted subjectively (Q 286). In supplementary evidence, the UK bioscience sector has voiced concern that excessively restrictive interpretations could lead to repeated legal challenges which would significantly delay research (p 5).
52. Conversely, for the Dr Hadwen Trust, Ms McIvor recognised the difficulty of eliminating research using non-human primates, but commented that: "... as a very first step, purely speculative research where there is no medical

application seems like a good place to start and I would like to see that research prohibited in the terms of the legislative text” (Q 327).

53. Speaking for the BUAV,¹³ Dr Katy Taylor set out the case for ending all use of non-human primates in medical research, and claimed that there was a paucity of scientifically gathered evidence which supported the use of primates in safety studies. “What we need to remember ... is that we are not trying to replace a model that works; in fact, we believe that there is plenty of evidence to suggest that the model should be scrapped regardless of the presence or absence of alternatives” (Q 355). A similar argument was advanced by the representatives of Animal Defenders International,¹⁴ who pointed to the specific example of functional magnetic resonance imaging (fMRI) techniques (sponsored by ADI at Aston University) as a “viable alternative” to the use of non-human primates for the purposes of research into brain disease (Q 381).
54. The evidence that we took from the Commission’s representative threw more light on this issue. Ms Louhimies told us that the overall presentation of the restrictions in the proposal meant that the impact on current research was not likely to be as sharp as had been claimed by some. She stressed that the limitations in Article 8 should be understood by reference to text contained in Recital 16 of the proposal, which mentions “clinical conditions having a substantial impact on patients’ day-to-day functioning”. Ms Louhimies stated the Commission’s view that “for example, infertility could be considered in this category. We have references to it being considered as a debilitating condition, and we know that infertility can result in depression and it can result in psychosomatic disorders” (Q 19).
55. Lord Brett re-affirmed the Government’s opposition to the inclusion of limitations tied to specific clinical conditions. Taking the UK approach as an exemplar, he said that the Government considered that the use of non-human primates would be properly controlled by a robust ethical evaluation process. If any such use also had to be justified against its relevance to specific conditions, there was a risk of confusion which could delay or prevent important research (Q 481). **For our part, we firmly support a robust ethical review process in the case of all species used in scientific procedures, but we see the need to go further in respect of non-human primates.**
56. Our witnesses were divided in their views about the utility of research on non-human primates in improving scientific understanding of human diseases, and about the impact of the proposed restrictions. **While we recognise that, at present, there is a need to continue the use of non-human primates in research, we think that it is appropriate for the revised Directive to set clear limits beyond those applicable to other species. In the light of the evidence which we heard from the Commission’s representative, we are persuaded that the proposed restriction of such use to life-threatening or debilitating clinical conditions in Article 8 strikes the right balance between animal welfare and scientific research. While the wording of Article 8 could be clarified to reflect the understanding in Recital 16 that these conditions include those which have a substantial impact on patients’ day-to-day functioning, we would still look to the new Directive to place tighter limits on the use of non-human primates than on the use of other species.**

¹³ The BUAV (British Union for the Abolition of Vivisection) campaigns to end animal experiments.

¹⁴ ADI works for the suppression of all forms of cruelty to animals.

BOX 4

Statistical Information about the Use of Non-Human Primates in Britain

In Britain in 2008, 3354 non-human primates were used for the first time in scientific procedures regulated under the Animals (Scientific Procedures) Act 1986 (0.09% of the total use of animals under the Act in that year).^(a)

The majority (92%) of these non-human primates were macaque monkeys (3092 animals); and the others were either marmoset or tamarin monkeys (262 animals).

The major use of the macaques was in evaluating the safety or efficacy of pharmaceuticals (82% were used for this purpose) or for method development or validation in this area (12%); and 2% were used in other “applied” studies.^(b) 122 macaques (4% of the total in 2008) were used in “fundamental” biological research,^(c) mainly in the fields of microbiology, physiology and immunology.

By comparison, 31% of marmosets and tamarins (82 animals) were used in fundamental biological research; 20% in pharmaceutical safety evaluation (53 animals); 27% in method development or validation; and 22% in other applied work.

In Britain, non-human primates have not been used for safety tests on non-pharmaceutical products since 1998, when 40 marmosets or tamarins were used to test substances intended for use in industry. Macaques have not been used for such testing since 1997, when 8 were used to test substances intended for use in agriculture.

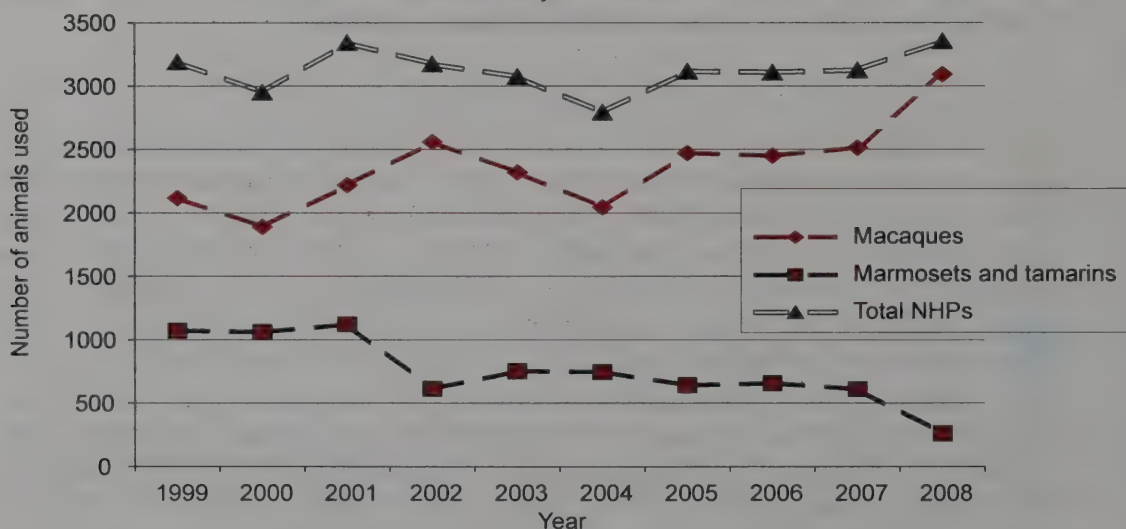
Figure 1 shows the pattern of use of non-human primates in Britain over the past 10 years. It can be seen that total use has hovered around 3000 animals; but in recent years the use of macaques has increased, whilst use of marmosets has decreased.

(a) See Home Office statistics of scientific procedures on living animals in 2008.

(b) Studies to develop or test products or devices for human medicine or dentistry, or veterinary medicine.

(c) Studies aimed solely at an increase in knowledge, or with a view to providing a practical solution to a medical or veterinary problem once the issues are more clearly defined and understood.

FIGURE 1

Regulated use of non-human primates (NHPs) for research and testing in Britain, 1999–2008

This graph shows the number of animals used for the first time in each year.

Home Office statistics also record the number of procedures performed on these animals. In any given year, the number of procedures is higher than the number of animals recorded because some animals are used more than once (when the procedures they are involved in have only minimal effect, for which anaesthesia is not required).

In 2008, macaques were used in 4,230 procedures, and marmosets in 368.

Limitation of use to offspring of animals bred in captivity

57. Article 10 of the Commission's proposal provides that, after deadlines specified in Annex III, the use of non-human primates will be limited to the offspring of non-human primates which have been bred in captivity ("F2 animals"). The deadlines vary according to species. In advancing these proposals, the Commission has pointed both to animal welfare issues (such as the stress caused to animals by capture from the wild and the risk of injury), and to scientific considerations (the improved quality and reliability of results from animals bred specifically for use in procedures). In the UK, non-human primates must be obtained from designated breeding or supplying establishments, or from overseas (or other non-designated) sources acceptable to the Home Office; and the use of wild-caught non-human primates is prohibited, other than where exceptional and specific justification can be established.¹⁵ Marmosets and tamarins are currently bred in captivity to at least the F2 generation. The main issue lies in the supply of macaques, which are imported to the EU from source countries in the Far East. (See Box 5)
58. We asked the Commission's representative to explain the thinking behind the proposal of specific deadlines. Ms Louhimies said: "We want to make a push; without putting anything in the Directive the status quo would be highly unlikely to change, so we need the push there, but we build it in a flexible manner, so that, in case we need to, we can go back and we can revise these deadlines" (Q 21).¹⁶
59. This approach was strongly supported by the RSPCA, who drew attention to the precedent of the Cosmetics Directive¹⁷ which set deadlines for ending animal testing of cosmetic products and ingredients within the EU. Mr David Bowles stressed the effectiveness of finite deadlines in legislation: the Cosmetics Directive did not simply rely on "a lot of fine words ... until there was a deadline included, nothing actually happened in terms of moving away from testing on cosmetics" (Q 156). For the Dr Hadwen Trust, Dr Gemma Buckland also pointed to the precedent of the Cosmetics Directive (Q 329).
60. In the event, as the RSPCA pointed out, the deadline originally specified for ending animal-testing for cosmetics was put back, from 1998 to 2009, in the light of the rate of scientific development. However, the deadline had now finally been implemented (Q 159).
61. When we questioned the ABPI's representatives, they voiced support in principle for a move to F2 animals, but emphasised the difficulties of a fixed timetable: "The issue is how to move to self-sustaining F2 colonies without causing major welfare and supply problems ... We support the European Parliament position here in calling for a full feasibility study rather than the seven-year prescriptive time limit which the Commission's original proposals put in place" (Q 97).
62. Academic representatives voiced their reservations about the proposal, both on scientific and feasibility grounds: "The first thing to say is that there is actually no evidence that suggests that animal welfare is any better by using F2; in other

¹⁵ Home Office (2000): Guidance on the Operation of the Animals Scientific Procedures Act 1986 (HC 321, TSO: London).

¹⁶ Annex III may be adapted in accordance with Article 48.

¹⁷ Directive 76/768/EEC and its 7th Amendment through Directive 2003/15/EC. From 11 March 2009, no animal testing of cosmetics has been permitted in the EU.

words, entirely captive-bred animals compared with others. The second thing to say is that in principle it does seem a sensible direction in which to move; but we are a long way from having the capacity to do that and, frankly, it remains enormously expensive” (Q 225). The Home Office pointed out that, since EU use of F2+ animals represented only about 5% of the total market, it was “unlikely this will be achieved within seven years or without considerable investment and ongoing costs” (p 193). We also received a written submission from the Mauritian Cyno Breeders Association (suppliers of cynomolgus monkeys) which claimed that a move to F2 colonies would adversely affect the research community, both in terms of price and animal quality (p 237).

63. **We endorse the aspiration that use of non-human primates should be restricted to F2 animals, and it may be that this can be achieved against the time-limits in Annex III of the proposal. However, given the degree of uncertainty related to the practicality of this suggestion, we consider it crucial that this aspect of the Directive be monitored closely: it must be sensible that the feasibility of the time-limits should be reviewed, on a species-by-species basis.**

BOX 5

Supply of F2 macaques: background information

The UK has a self-sustaining rhesus macaque colony (the Centre for Macaques), which supplies academic researchers. Industry mainly uses cynomolgus macaques which are generally obtained from sources outside the EU.

The main suppliers of cynomolgus macaque monkeys used in UK laboratories, and the EU as a whole, are in Mauritius, Vietnam and China. Facilities are also being developed in Cambodia. At present, macaques imported to the UK mostly come from Vietnam and Mauritius, in roughly equal proportions.

In Vietnam, and Cambodia, wild macaques have B-virus, but only B-virus negative animals can be held in the UK. These source countries have a virus elimination programme in which macaques are bred and maintained in closed, self-sustaining colonies; further introduction of wild-caught animals into the colonies would undermine these efforts.

In Vietnam, fourth-generation captive-bred animals are already available in significant numbers. In Cambodia one farm is already self-sustaining, but supply is only at F1 stage, and another such colony is being developed.

Cynomolgus monkeys are not indigenous to China (only rhesus monkeys), but here, too, B-virus is also a driver towards closed colonies. However, of 30–50 farms, very few can supply animals that are verifiably F2 or beyond.

Around 70% of macaques used in the EU as a whole are sourced from Mauritius, where the wild population is free from B-virus, and where wild macaques are considered a pest species. This means that there is little or no drive to move to closed, self-sustaining colonies, and colonies are sustained by bringing in breeding females captured from the wild (using methods not subject to government regulation), in numbers equivalent to around one-tenth of the total colony size annually. It is clear that there are some F2 animals available from Mauritius, but they are not distinguished from F1 at present.

Mauritian suppliers have expressed a willingness to move to supply F2 animals to Europe (but not necessarily globally), and (subject to concerns expressed in the evidence from the Mauritian Cyno Breeders’ Association) should be able to do so at some future date, yet to be determined.

CHAPTER 4: DATA-SHARING AND AUTHORISATION

Data-sharing

64. Article 44 of the proposal addresses the “unnecessary duplication of procedures”. It provides (at Article 44(1)) for mutual acceptance between Member States of data from tests required under Community legislation, so that, for example, vaccine batch-testing done in one EU country should not have to be repeated in another. Article 44(2) goes further, and provides for data generated by procedures to be shared, subject to safeguarding confidential information.
65. As regards Article 44(1), many of our witnesses considered mutual acceptance of data between Member States to be highly desirable. For the RSPCA, Dr Jennings expressed the view that greater harmonisation of standards and acceptance of data between countries would benefit animals (Q 200); for EFPIA, Ms Chlebus endorsed the principle underlying Article 44 (Q 437).
66. There is an important difference between duplication on the one hand, and replication on the other. While duplication may be unnecessary and should therefore be minimised, replication of procedures may very well be justified in order to provide assurance of scientifically useful findings.
67. We asked the Commission’s representative where any duplication was thought to occur, and how readily such duplication could be remedied by proposals for data-sharing. Ms Louhimies’ responses suggested that further thought might need to be given to this aspect. She told us that, as regards basic research, the only evidence of unjustified duplication might be “in the areas where research results are ‘negative’, meaning that I have a hypothesis at the start of my project but my hypothesis has not proven to be correct” (Q 40). Given that universities were competing for funding not only in the EU but internationally, Ms Louhimies said that it would be “very problematic” to bring about greater sharing of negative data from basic research (Q 42).
68. We encountered scepticism among our witnesses about the extent of duplication, and about the viability of data-sharing as envisaged in the proposal. Sir Mark Walport, of the Wellcome Trust, stressed his sector’s support for sharing data in relation to properly completed research, but said: “The idea that every piece of data about every animal experiment should be made available would neither improve animal welfare nor would it realistically increase transparency” (Q 211).
69. For the ABPI, Professor Hammond spoke of the potential commercial risks that could result from any enforced sharing of data from incomplete research, for example, into the active ingredients of new drugs: “If we are forced to put that into the public domain, we cease to become a competitive industry ... it will simply mean that everyone else outside of Europe will have access to all our intellectual property and we will not have access to theirs. It would be absolutely untenable” (Q 85). We note from the written evidence submitted by the bioscience sector that a range of data-sharing initiatives are already well-established (p 35). Dr Robinson, of the NC3Rs, commented that, while there were gains to be made from data-sharing, there were issues of confidentiality, and that volunteering of information would be better than compulsory disclosure (Q 280).

70. At First Reading in May 2009, the European Parliament proposed a number of amendments¹⁸ which significantly expanded the data-sharing requirements of Article 44, including placing requirements on those applying for the authorisation of procedures to check on the existence of relevant data, and on Member States to carry out similar checks before deciding on such authorisation.
71. **We agree that the mutual acceptance between Member States of data from tests required under Community legislation is highly desirable; and we consider that Member States should implement legislation to ensure that, at least, the use of animals for ratification of such data will be sanctioned only in exceptional circumstances and for strictly scientific reasons.**
72. **We consider that the case has not been made that there is widespread duplication of procedures. In the absence of cogent evidence, and bearing in mind the principle of proportionality, we have reservations about the provisions of Article 44(2). By the same token, we consider the European Parliament amendments on data-sharing to be undesirable.**

Authorisation

73. Experience of the inconsistent implementation of the 1986 Directive raises the question of how best to ensure effective implementation of a revised Directive across all Member States. We deal with this at the end of this Chapter.
74. However, this issue emerged less forcefully from the evidence than a concern that the adoption of the procedures and standards contained in the proposal would impair the competitiveness of European companies vis-à-vis their counterparts elsewhere in the world. A recurrent fear voiced by representatives of the UK pharmaceutical industry and research community was that the control regime would be over-bureaucratic; their comments reflected their experience of working within the framework of the Animals (Scientific Procedures) Act 1986.
75. By way of context, we were told by representatives of EFPIA that 80% of all vaccine research, development and manufacturing for the worldwide market was done in Europe; that pharmaceutical investment in R&D constituted 19% of all private research and development investment in Europe; that the pharmaceutical industry across Europe employed 635,000 people, of whom 117,000 were directly employed in R&D; and that the European pharmaceutical sector had a trade surplus of €52 billion (QQ 393 and 394).
76. Speaking for the Commission, Ms Louhimies rejected suggestions that regulation would prove anti-competitive. She said that the Commission had no evidence that research in the pharmaceutical industry had been transferred outside the EU as a result of high standards of animal welfare or a strict regulatory environment; and she pointed to the example of the UK, with some of the highest standards in the EU, but also a large and profitable industry (Q 32).

¹⁸ Amendments 132, 180, 134, 135, 136 and 137

77. However, Ms Louhimies acknowledged the importance of delivering regulation in an effective and efficient manner, which was reflected in the inclusion in the proposal (at Article 43) of a deadline for a decision on an authorisation to be reached within 30 days of application (or 60 days in exceptional circumstances). She said that, in an environment of global competition, it was right to ensure that industry and the research community in the EU were not disadvantaged by extremely long implementation of authorisation deadlines. At the same time, Ms Louhimies stressed that, since implementation would fall to the Member States, they would have a key role in ensuring the efficiency of the regulatory arrangements (Q 11).

UK regulatory environment

78. The purpose of this inquiry has not been to review the working of the regime for controlling animal procedures in the UK, but experience of that regime underlay evidence that we heard. Speaking for the academic community, the picture which Professor Max Headley, of the University of Bristol, painted of the UK system emphasised the difficulties that resulted from the imposition of restrictions and the requirement for detailed information: “There have been and continue to be significant problems with the implementation of ... the Animals (Scientific Procedures) Act. It is very restrictive and that causes enormous frustration. If you are doing an experiment today as an innovative scientist, you want to be able to modify in the light of today’s experiment what you do tomorrow. Not to be able to do so without having to go through the application procedure for amendments and obtaining appropriate approval to do so causes enormous delays.” He acknowledged, however, that in the last couple of years the Home Office had started to reverse that trend by reducing the amount of information that was required in licences (Q 214).
79. A perception of the UK system of controls as slower and more complex than that of other countries was also apparent in comments by the ABPI, and in their concern that implementation of the revised directive would prove overly bureaucratic. Professor Hammond said: “The time [needed to obtain an authorisation] in the UK is considerably longer and the process more complex than it is in other European Member State countries currently. It is more difficult to respond in those timescales that are applicable in the UK than it is in Europe, and Europe is considerably more difficult than the USA, and the USA is probably a little bit slower than Asia” (Q 70).
80. While other witnesses recognised that there could be delays in the UK system, several of them argued that the authorisation process in this country worked better than had been suggested by industry and academic representatives.
81. Dr Robinson, for the NC3Rs, said that “an enormous amount of work has been put into reducing the level of paperwork and the time it takes to get a licence” (Q 295). Ms Jan Creamer, Chief Executive of Animal Defenders International, pointed out that “the Home Office has said that 85% of their project licence applications are awarded in 35 days and their average is 18 days” (Q 376). The Home Office’s Animal Scientific Procedures Inspectorate and Division’s Annual report for 2008 (published in July 2009)¹⁹ shows a further improvement in these turnaround times.

¹⁹ See: http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/reports-and-reviews/ASPI_Annual_Report_2008.pdf?view=Binary

82. For the RSPCA, Dr Jennings saw three main steps that could help make the UK system of authorisation more efficient: providing better guidance on completing project licence applications; improving the efficiency of ethical review processes; and enhancing the education and training of prospective licence-holders. “There is therefore a package of measures that can improve upon the whole application process and the time it takes” (Q 153).
83. We raised these issues with the Home Office. Lord Brett told us that his Department was working closely with those whom it regulated in order to apply better regulation principles in this area, and that it was, for example, about to launch a new project licence application form which would require less information (Q 473). Dr Richmond said that, while the application process was still paper-based, the Home Office was taking forward plans to move to an IT-based system which could further reduce the turnaround time for applications by 4 or 5 days (Q 478).

Authorisation or notification

84. The Commission’s proposal envisages that all procedures would require prior authorisation, regardless of their severity classification. In order to introduce greater flexibility into the system, the bioscience sector has put the case that “mild” procedures should be notified in advance to the relevant authorities following favourable evaluation by the ethical review process, but should not require explicit prior authorisation by the competent authority. The written evidence from the bioscience sector stated that a notification process would allow “rapid progression of projects or amendments where harms to the animals are minimal and ethical evaluation at a local level has been favourable.” The competent authority would have the opportunity to intervene if any concerns arose, but this approach would allow that authority and the establishment “to focus effort on those projects and procedures involving greater pain, suffering, distress or lasting harm” (p 29).
85. Some of our witnesses voiced trenchant concern about this suggestion. Ms McIvor, for the Dr Hadwen Trust, told us that such a change would be “an enormous weakening” of current UK controls (Q 334). Similarly, Dr Jennings, for the RSPCA, commented: “Of all the suggested amendments and suggestions for changing the Directive, it is probably the thing that concerns the RSPCA most. We feel that would be a serious step back in the regulation of animal experiments in the UK” (Q 180).
86. The Animals Procedure Committee (APC)²⁰ advises the Home Office on matters concerned with the Animals (Scientific Procedures) Act. On the specific issue of notification rather than authorisation of mild procedures, the APC noted that its members’ views were divided. More generally, however, the APC commented that in the UK the 1986 Act was widely regarded as promoting good standards of animal care and use: “... the APC believes that the standards within the ASPA should not be weakened or compromised in any way as a result of the Directive revision” (p 222).
87. For the Home Office, Mr Martin Walsh told us that negotiations under the Presidency seemed unlikely to incorporate a notification procedure in the proposal, but that the Presidency was considering how best to accommodate

²⁰ The Animal Procedures Committee (APC) is an advisory Non-Departmental Public Body established and appointed under the terms of sections 19 and 20 of the Animals (Scientific Procedures) Act 1986.

different approaches followed by different Member States, and this might include the possibility of “tacit approval” (Q 469). Dr Richmond said that the Government supported a proportionate approach in the handling of applications; while all would be subject to ethical review, simpler applications could thus be treated more simply (Q 470).

88. It has been a consistent theme of the evidence received that high standards have been achieved in the UK under the 1986 Act. While the UK would not be directly obliged to apply any lower standards adopted in a new Directive, there could be commercial pressure to do so. We recognise that other Member States have different approaches which may not readily match the arrangements in the UK. Differences are acceptable so long as they do not imply lower standards of animal welfare; the revision of the Directive should be seen as an opportunity to level up. **We are concerned over the concept of “tacit approval” which, in our view, may open the way to importing notification arrangements into the control regime. We therefore support the authorisation requirements set out in the Commission’s proposal and reject any move to require notification, or tacit approval (rather than authorisation), for “mild” procedures.**

Authorisation and competitiveness

89. On the issue of whether the EU would continue to be a competitive environment for the location of pharmaceutical research and development, we heard a balanced view from Dr Gabriele Kuesters, of EFPIA: “What really attracts companies are other factors, like access to capital for investment, the high skills of personnel, and sometimes even tradition plays an important role.” At the same time, Dr Kuesters stressed that, while unnecessary bureaucratic burdens that did not improve animal welfare might not be decisive, they were an additional factor when decisions had to be taken on new investments (Q 410).
90. From a standpoint of strong advocacy of the use of alternatives to animals, Mr Helder Constantino, for the ADI, addressed the issue of competitiveness from another perspective: “... when a company or a laboratory invents a new alternative the alternative becomes the property of the company, so it can become a commercial market.” He offered an example highlighted by European Commissioner Günter Verheugen, namely alternative methods developed to replace the rabbit pyrogen test for bacterial impurities in drugs: “[these] had proved a major success and had a worldwide market volume of €200 million, so that is a key example where companies and business can benefit from making alternatives” (Q 376).
91. We recognise that the proof of whether the revised directive hampers the EU’s competitiveness will emerge from its implementation. We note the view expressed in a letter of September 2009 from Sir Leszek Borysiewicz, Professor Max Headley and Sir Mark Walport that evidence of substantive further movement out of the EU was likely to emerge only after the Directive had been implemented. We do not share the apprehension that implementation of the Directive will inevitably lead to the imposition of bureaucratic burdens that are not justified by any gain in animal welfare, but it must be right to minimise the risk of that outcome. **We support calls for the authorisation processes contained in the proposal to be justified by the scientifically demonstrated needs of animal welfare.**

92. Authorisation processes must be efficient, so that scientists in both industry and academia can take on new lines of inquiry and amend current approaches without undue delay. **In our view, this means that the ethical review process proposed must be dovetailed into the procedure, including specifying time-limits for that process which are consistent with the 30-day time-limit for the authorisation process as a whole.**

Implementation—inspection and review

93. We return to the question of whether a revised Directive will in practice be implemented consistently across the EU. This has not been the case with the 1986 Directive, and both Member States and the Commission bear responsibility for this. So it is essential that this unsatisfactory experience is not repeated with a new Directive.
94. Ms Louhimies stressed the responsibility of the Member States for implementation, but she also highlighted the fact that the Commission's proposal required Member States to carry out two inspections of relevant sites each year (one unannounced) and that the Commission would monitor national inspection arrangements (Q 10).
95. We heard differing views on how to achieve consistent implementation. Sir Leszek Borysiewicz (MRC) commented that this would best be secured by ensuring that the revised directive was “bought into by the widest possible community in Europe”, with the result that any departure from the standards agreed would readily be exposed to public scrutiny (Q 264). Conversely, Ms Emily McIvor, for the Dr Hadwen Trust, supported a more interventionist approach, calling for an EU Inspectorate to oversee consistency among Member States in the implementation of severity classifications (Q 331).
96. Lord Brett told us that the Government expected greater harmonisation across the EU to flow from the provisions on authorisation and ethical review, and on care and accommodation standards. However, he said that the Presidency's efforts to maximise support for the proposal had raised the possibility that the new Directive would not specify a minimum frequency for national inspections (Q 488). As regards the Commission's role, Dr Richmond told us that the Commission intended that implementation should be “resource-neutral” (Q 492). For our part, we consider it essential that the Commission should bring an energy to monitoring implementation of a new Directive which has not been apparent in the case of the 1986 Directive.
97. **Given the importance of ensuring the application of common standards across all Member States, we firmly endorse the need for effective national inspection arrangements, including a minimum frequency which ensures that all relevant sites are visited at least once a year.** But we see a case for going further. The European Parliament agreed amendments²¹ to the proposal to strengthen the role of the Commission in overseeing implementation. We consider that the Commission should be robust in performing this role, and we are concerned that this role could be weakened in negotiations on the proposal. Mindful of the inconsistency with which the 1986 Directive has been implemented, **we support the European Parliament amendments which would oblige, rather than**

²¹ Joint amendments 186 and 176 to Article 34.

permit, the Commission to undertake controls of the infrastructure and operation of national inspections in Member States. Without this, we fear that a new Directive will do little to remedy the widely varying approaches of Member States, including standards of animal welfare, which currently exist.

98. We note the concern expressed in the letter of September 2009 from Sir Leszek Borysiewicz and his co-signatories that any such enhanced role for the Commission should not extend to the inspection of documents held by national competent authorities: in their view, this would be bureaucratically burdensome and could compromise intellectual property rights and, possibly, data protection. We do not share that view: inspection of documents may well prove necessary in the interests of securing consistent implementation, which is a driving force behind the proposed revision of the existing Directive.
99. Central responsibility for implementation rests with the Member States. We think that it is important that they submit information on implementation sooner than six years after the transposition date. **The Commission should review the Directive no later than five years after it has come into force (and not ten, as proposed).**

CHAPTER 5—CONCLUSIONS AND RECOMMENDATIONS

100. We agree that the 1986 Directive should be revised; a new Directive should contain effective safeguards to ensure consistent implementation. (para 15)

Scope

101. Based upon the available scientific knowledge about sentience, we consider that, while cephalopods should be included, decapods should be excluded. We also take the view that independently feeding larval forms of invertebrates should be excluded. We consider that cyclostomes should be included. (para 19)
102. We think that it should be possible for the emergence of new scientific evidence pertaining to sentience to lead relatively readily to the inclusion (or exclusion) of invertebrate species in the control regime of the Directive; we would hope that further consideration of the framing of these provisions would allow a more flexible approach to be followed. (para 20)
103. We support the proposal that independently feeding larval forms and embryonic or foetal forms (from the last third of their normal development) of live non-human vertebrate animals would also be included. (para 21)
104. The provisions of the Directive should be amended to ensure that the breeding and humane killing of animals for their tissues and organs should not be regarded as a “project” within the terms of the Directive. While the care and welfare of these animals should be ensured, we regard it as disproportionate to require that work involving them should be subject to the authorisation processes required of projects. (para 23)

Severity classifications

105. We consider that the definitions for severity classifications proposed in July 2009 by the expert working group could appropriately be adopted in the revised directive. (para 25)
106. The European Parliament amendments to Article 15 allowing exceptions to the prohibition on prolonged severe procedures imply a lower level of animal welfare than is currently maintained in the UK. We would see any such change as unacceptable. (para 26)

Re-use

107. The re-use provisions must be amended in order to avoid unintended consequences for animal welfare. As presented in the Commission’s proposal, the provisions would be likely, in certain specific circumstances, to increase the number of animals and degree of suffering that would need to be used. (para 31)

Care and accommodation standards

108. The timescale for implementation of these standards in the academic sector should be extended. We think that the timescale for the introduction of the stocking densities proposed for rodents at breeding establishments should also be extended, since it is unclear that the resulting increase in cage sizes will offer any measurable animal welfare benefits. More generally, we accept the case

made to us that explanatory text which accompanied the standards as first embodied in Council of Europe guidelines should be restored. (paras 39, 40)

Promotion of the 3Rs

109. We support the general promotion of the 3Rs: the replacement, reduction and refinement of the scientific use of animals, through the development and implementation of relevant methods. The specific proposal that national reference laboratories be set up is too prescriptive; we see a risk that such a centralised model would fail to draw on the expertise and innovation that are found in the wider scientific community. We are persuaded that a system of national centres along the lines of the UK's National Centre for the 3Rs might well be a better route to follow. (para 47)

Use of non-human primates in research

110. We firmly support a robust ethical review process in the case of all species used in scientific procedures, but we see the need to go further in respect of non-human primates. While we recognise that, at present, there is a need to continue the use of non-human primates in research, we think that it is appropriate for the revised Directive to set clear limits beyond those applicable to other species. In the light of the evidence which we heard from the Commission's representative, we are persuaded that the proposed restriction of such use to life-threatening or debilitating clinical conditions in Article 8 strikes the right balance between animal welfare and scientific research. While the wording of Article 8 could be clarified to reflect the understanding in Recital 16 that these conditions include those which have a substantial impact on patients' day-to-day functioning, we would still look to the new Directive to place tighter limits on the use of non-human primates than on the use of other species. (paras 55, 56)
111. We endorse the aspiration that supply of non-human primates should be restricted to F2 animals, and it may be that this can be achieved against the time-limits suggested in Annex III of the proposal. We consider it crucial that this aspect of the Directive be monitored closely, and that the feasibility of the time-limits should be reviewed on a species-by-species basis. (para 63)

Data-sharing

112. Mutual acceptance between Member States of data from tests required under Community legislation is highly desirable; we consider that Member States should implement legislation to ensure that, at least, the use of animals for ratification of such data will be sanctioned only in exceptional circumstances and for strictly scientific reasons. (para 71)
113. We consider that the case has not been made that there is widespread duplication of procedures. In the absence of cogent evidence, and bearing in mind the principle of proportionality, we have reservations about the provisions of Article 44(2). By the same token, we consider the European Parliament amendments on data-sharing to be undesirable. (para 72)

Authorisation

114. We are concerned over the concept of "tacit approval" which, in our view, may open the way to importing notification arrangements into the control regime. We therefore support the authorisation requirements set out in the

Commission's proposal and reject any move to require notification, or tacit approval (rather than authorisation), for "mild" procedures. (para 88)

115. We support calls for the authorisation processes contained in the proposal to be justified by the scientifically demonstrated needs of animal welfare. (para 91)
116. The ethical review process proposed must be dovetailed into the procedure, including specifying time-limits for that process which are consistent with the 30-day time-limit for authorisation. (para 92)

Inspection and review

117. Given the importance of ensuring the application of common standards across all Member States, we fully endorse the need for effective national inspection arrangements, including a minimum frequency which ensures that all relevant sites are visited at least once a year. We support the European Parliament amendment which would oblige, rather than permit, the Commission to undertake controls of the infrastructure and operation of national inspections in Member States. Without this, we fear that a new Directive will do little to remedy the widely varying approaches of Member States, including standards of animal welfare, which currently exist. (para 97)
118. The Commission should review the Directive no later than five years after it has come into force (and not ten, as proposed). (para 99)

APPENDIX 1: SUB-COMMITTEE D (ENVIRONMENT AND AGRICULTURE)

The members of the Sub-Committee that conducted this inquiry were:

The Earl of Arran
 Lord Brooke of Alverthorpe
 Viscount Brookeborough
 The Earl of Caithness
 Lord Cameron of Dillington
 Lord Carter of Coles (from July 2009)
 The Earl of Dundee
 Baroness Jones of Whitchurch (up to July 2009)
 Lord Livsey of Talgarth
 Lord Palmer
 Lord Sewel (Chairman)
 Baroness Sharp of Guildford
 Viscount Ullswater

Declarations of Interest Relevant to this Inquiry

The Earl of Arran
Married to a farmer and landowner in Devon
Trustee of certain family trusts associated with farming

Lord Brooke of Alverthorpe
No relevant interests

Viscount Brookeborough
Farmer

The Earl of Caithness
No relevant interests

Lord Cameron of Dillington
Farmer and landowner
Board Member of the Royal Bath and West Agricultural Society
Trustee of the Lawes Agricultural Trust
Member of the Country Land and Business Association
Member of the National Farmers' Union

Lord Carter of Coles
Farmer and landowner

The Earl of Dundee
Farmer, landowner and forester in Scotland
Director of farming company in Scotland
In receipt of Single Farm Payments

Baroness Jones of Whitchurch
No relevant interests

Lord Livsey of Talgarth
Vice President of the Brecknock Federation of Young Farmers Clubs
Member of the Royal Welsh Agricultural Society
Associate of the British Veterinary Association

Lord Palmer
Arable farmer with let grazing for animals including horses, with let forestry for game shooting etc.
Member of the National Farmers' Union Scotland

Member of the Scottish Country Land and Business Association
Registered Diabetic, insulin dependent
In receipt of Single Farm Payment and Rural Stewardship Schemes etc.

Lord Sewel

In receipt of a pension from the Universities Superannuation Scheme
Wife is employed by the University of Aberdeen in an administrative capacity

Baroness Sharp of Guildford

No relevant interests

Viscount Ullswater

Trustee of landed estates in Cumbria and Devon (Expenses)
Member of the Country Land and Business Association

A full list of Members' interests can be found in the Register of Lords Interests:

<http://www.publications.parliament.uk/pa/ld/ldreg.htm>

APPENDIX 2: LIST OF WITNESSES

The following witnesses gave evidence. Those marked * gave oral evidence.

- Animal Aid
- * Animal Defenders International (ADI)
- Animal Procedures Committee
- * Association of the British Pharmaceutical Industry (ABPI)
- * British Union for the Abolition of Vivisection (BUAV)
- * Dr. Hadwen Trust for Humane Research
- * European Commission (Directorate-General Environment)
- * European Federation of Pharmaceutical Industries and Associations (EFPIA)
- * Home Office
- Huntingdon Life Sciences
- Kings College London
- Laboratory Animal Breeders Association
- * National Centre for the 3Rs
- Noveprim
- Open University
- Professor John M. Pearce, FRCS
- * Royal Society for the Prevention of Cruelty to Animals
- Universities Federation for Animal Welfare
- * UK Biosciences Federation
- Uncaged

APPENDIX 3: CALL FOR EVIDENCE

Introduction

The House of Lords European Union Committee will be conducting an inquiry, through its Environment and Agriculture Sub-Committee (Sub-Committee D), into the proposal for a repeal and replacement of the EC Directive governing the protection of animals used in research.²²

In 1986, the European Community adopted a Directive on the protection of animals used for experimental and other scientific purposes. The European Commission argues that the Directive, now over 20 years old, does not cater for modern techniques in the field of animal experimentation, nor does it take account of the latest developments in animal welfare.

In 1997, the EC adopted a Protocol (No. 33) on animal welfare, which describes animals as 'sentient beings', and instructs the EC and its Member States to 'pay full regard' to the welfare requirements of animals in formulating and implementing their internal market and research policies (among others). The Commission suggests that the current provisions of the Directive no longer meet this obligation.

Moreover, there has been wide variation in national implementation of the 1986 Directive, due to ambiguities and inconsistencies in the current provisions of the text.

The Commission therefore proposes to repeal the 1986 Directive and replace it with a new Directive, with two aims:

- To ensure a level playing field within the EU for industry and the research community by laying down harmonised common rules
- To strengthen the protection of animals still used in scientific procedures in line with the Protocol on Animal Welfare

The Committee is seeking evidence from stakeholders and other interested parties on the draft legislation, on the basis of which it will formulate conclusions and recommendations designed to inform the House of Lords and assist the UK Government and the EU institutions in finalising the content of the Directive.

The issues

Against this background, the Committee hereby invites you to submit written evidence to its Inquiry. The Committee would find it helpful if you would focus on a number of specific issues, listed below. You may also wish to draw to our attention to additional issues not addressed by the questions below, to the extent that those additional issues relate to the provisions of this draft Directive. It is recognised that those submitting evidence will not necessarily have an interest in all the questions and may therefore wish to be selective.

Views are sought on the following:

²² COM (2008) 543. See also the Commission's Q&A on the proposal: MEMO/08/677 of 5 November 2008.

Objectives of the Directive

- (1) What degree of harmonisation of rules governing the protection of animals in research is required to avoid distortions of the Single Market? To what extent are such distortions causing problems at present, and is the draft Directive a proportionate response to those problems?

International competition

- (2) How might high(er) animal welfare standards in the EU impact upon the international competitiveness of the EU's private and public sector research base, and that of commercial establishments carrying out routine testing? Is there a risk of displacing research using animals to third countries and, if so, what would be the consequences of such a trend?

The proposed requirement to restrict research on non-human primates (Art. 8)

- (3) Are the proposed restrictions proportionate, and what might be their impact?

Extension of the scope of the Directive (Art. 2)

- (4) Are the proposed extensions to the scope of the Directive justified, and what might be their impact?

Authorisation of Persons, Requirements for Establishments, Inspections and Project Requirements (Arts. 20–43)

- (5) Are the administrative demands that the draft Directive would impose overall proportionate to its objectives?
- (6) Do any of the provisions relating to the authorisation of persons, the requirements for establishments, the inspection regime, or project requirements require further consideration and/or amendment and, if so, why?

Care and Accommodation (Art. 32)

- (7) Are the care and accommodation standards set out in Annex IV to the Directive appropriate, and will they produce an adequate level of harmonisation across the EU?

Alternative Methods

- (8) How satisfactory are the provisions on alternatives to animal testing and National Reference Laboratories (Art. 46)?

Subsidiarity and Legal Base

- (9) Is it appropriate to regulate at the EU level—as opposed to lower tiers of government—in all of the proposed areas? Is the legal base for the proposal adequate in light of the content of the Directive?

APPENDIX 4: TRENDS IN USE OF ANIMALS IN SCIENTIFIC PROCEDURES IN BRITAIN

As Figure 2 shows, regulated scientific use of animals has steadily declined since the mid-70s, levelling off during the 1990s, and then rising year on year since 2000.

Figure 3, overleaf, shows that the recent increases are largely, but not entirely, attributable to rises in the breeding of GM and mutant animals in order to maintain colonies of these animals (so-called “breeding procedures”—the animals involved being “bred but not otherwise used”).

Figure 4, overleaf, suggests that, overall, much of the remaining increase is attributable to a rise in the use of animals in fundamental biological research and, to a lesser extent, in pharmaceutical R&D.

FIGURE 2
Total recorded use of animals in experiments/procedures 1945–2008



Figure 1: Experiments or procedures commenced each year, 1945-2008(1)

(1) Experiments under the 1876 Act or scientific procedures under the 1986 Act

(2) The experiments included in the 1987's figures also counted as procedures under the 1986 Act

²³ Home Office (2009) *Statistics of Scientific Procedures on Living Animals Great Britain 2008*.HC800.TSO: London.<http://www.homeoffice.gov.uk/rds/pdfs09/spanimals08.pdf>

FIGURE 3

Trends in breeding compared to all other procedures 1995–2008

Taken from Home Office (2009)²⁴

Millions of procedures

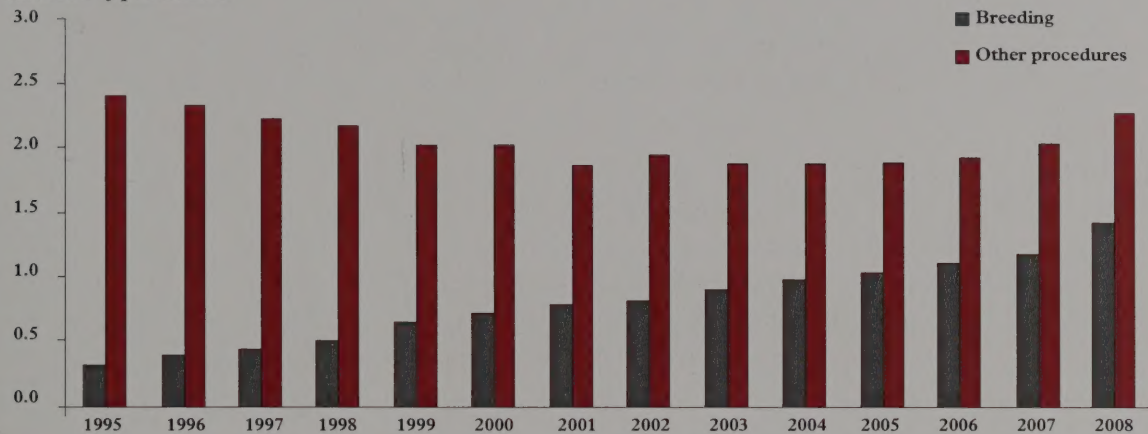
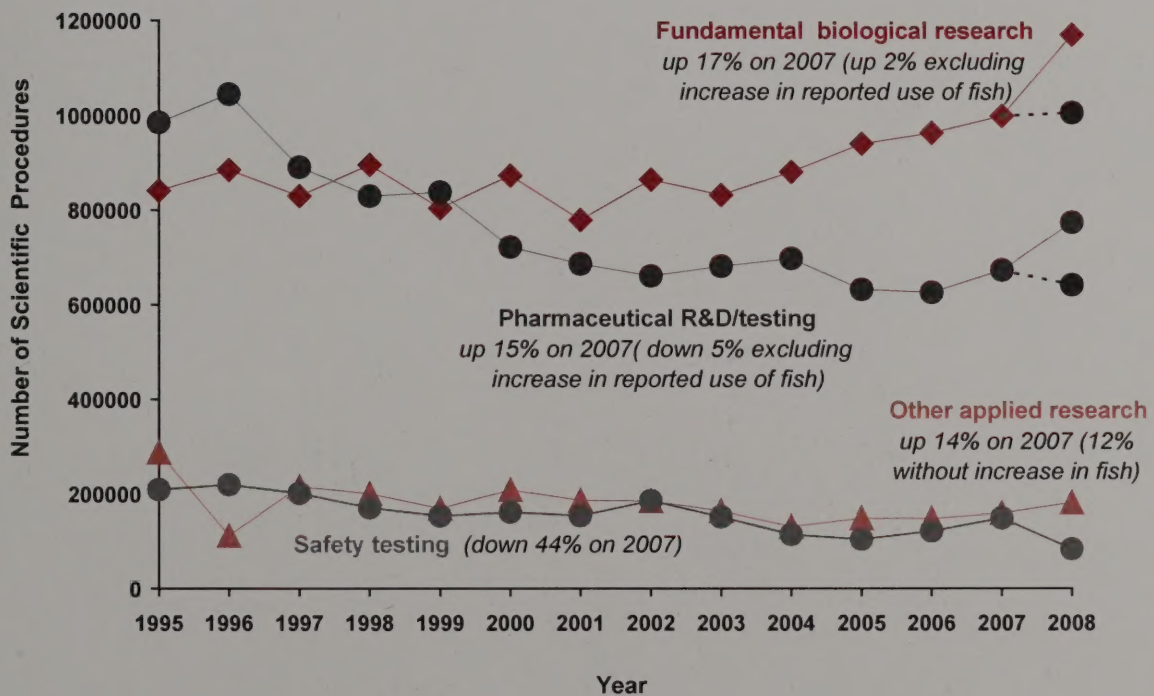


FIGURE 4

Trends in purposes of procedures other than breeding 1995–2008



As Figure 4 shows, there has been a general upward trend in the use of animals in fundamental biological research since 2001 and a general decline in the use of animals in pharmaceutical R&D since 1996, rising again from 2006.

As Figure 4 also notes, the large increases in non-breeding procedures for fundamental biological research and pharmaceutical R&D between 2007 and 2008 can chiefly be attributed to considerable increases in reported use of fish (up 85%

²⁴ Ibid.

between 2007–8). This is partly accounted for by a change in the stage of development at which fish fry are counted (Home Office 2009). The black spots in Figure 4 show data for these categories of use when the increase in use of fish is excluded. Overall, non-breeding procedures that do not involve the use of fish rose by 0.3% between 2007–8.



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